

The effect of local anaesthesia on postoperative pain and hemostasis after dental rehabilitation under general anaesthesia in pediatric patients

Submission date 31/12/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/01/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/03/2025	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Dental caries, also known as tooth decay, is a common disease that affects children. It has multiple causes and its treatment can be challenging, especially when the child is uncooperative. In such cases, dental treatment under general anaesthesia may be used. However, the use of local anaesthesia as an alternative is a controversial issue. The aim of the study is to investigate the effects of using local anaesthesia on post-operative pain and bleeding after dental treatment under general anaesthesia in children.

This research aims to study the effect of local anaesthesia on postoperative pain and hemostasis after Dental rehabilitation under general anaesthesia.

Who can participate?

Children of both genders aged three to seven years, described by Frankel's behavior rating scale as definitely negative.

What does the study involve?

The usage or not of local anaesthesia agents when treating children under general anaesthesia.

What are the possible benefits and risks of participating?

One of the benefits is the reduction in both pain and bleeding post-operatively as mentioned in some studies.

The risk of using local anaesthesia when treating children under general anaesthesia is an overdose of the used agent and the interaction with general anaesthesia agents.

Where is the study run from?

Al Bashir hospital (Jordan)

When is the study starting and how long is it expected to run for?

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Amal Batarseh, amal_batarseh@yahoo.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
The effect of local anaesthesia on postoperative pain and hemostasis after dental rehabilitation under general anaesthesia in pediatric patients aged from three to seven years old

Study objectives

Local anaesthesia effects on postoperative pain and hemostasis

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 20/02/2020, Scientific Research Ethics Committee (Ministry of Health, ALhashimi Alshamaly, Basman Erea, Hay Naifah, Next to Prince Hamazah Hospital, P.O.Box: 86, Amman, Jordan; +9625200230; no email provided), ref: Moh/REC/2020/44

Study design

Single-arm parallel-design single-blinded randomized controlled study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied

Post operative pain following dental treatment under general anaesthesia

Interventions

Forty-six boys and girls were included in this single-arm, parallel-design, single-blinded, randomized, controlled study. Before the commencement of the study, numbers from one to forty-six were randomly assigned as with local anaesthesia (LA) or without LA in closed envelope.

Group A: given LA which is (2% weight/volume (w/v) lidocaine with 1:80000 epinephrine) by calculating the dose according to the provided formula not exceeding 4.4 mg/kg.

Group B: not given any extra medication

Intervention Type

Procedure/Surgery

Primary outcome measure

Pain measured using:

1. Universal-pain-assessment-tool (UPAT) before the operation
2. FLACC behavior scale immediately after treatment, 30 min and 6 hours

Secondary outcome measures

Hemostasis measured using bleeding score obtained immediately after extraction using the Boezaart-surgical-field-grading-scale.

Overall study start date

15/01/2020

Completion date

01/03/2022

Eligibility

Key inclusion criteria

1. Aged three to seven years
2. Described by Frankel's behavior rating scale as definitely negative.
3. Arabic-speaking and healthy, with an American Society of Anesthesiologists (ASA) I or II classification

Participant type(s)

Patient

Age group

Child

Lower age limit

3 Years

Upper age limit

7 Years

Sex

Both

Target number of participants

46

Total final enrolment

43

Key exclusion criteria

1. Needing treatment or extraction of permanent teeth
2. Having an either medical, mental, or physical impairment
3. Need only restorative treatment without extraction or vice versa

Date of first enrolment

01/03/2020

Date of final enrolment

01/03/2022

Locations

Countries of recruitment

Jordan

Study participating centre

Al Bashir hospital

Amman

Jordan

-

Sponsor information

Organisation

Jordan Ministry of Health

Sponsor details

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diwan@moh.gov.jo

Sponsor type

Government

Website

<https://www.moh.gov.jo/>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/06/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

amal_batareseh@yahoo.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant flow diagram		04/01/2023	No	Yes
Other unpublished results			13/02/2023	No	No
Other unpublished results			13/02/2023	No	No
Results article		27/11/2023	12/03/2025	Yes	No